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WOLF GREENFIELD & SACKS, P.C.
600 ATLANTIC AVENUE
BOSTON, MA 02210-2206

| EXAMINER | |
|---|---|
| DELLA, JAYMI E | |

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/533,596 | FALWELL ET AL. | |
| | Examiner | Art Unit | |
| | JAYMI DELLA | 3739 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *30 November 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-11,13-43,74 and 95* is/are pending in the application.

4a) Of the above claim(s) *11,16-43,74 and 95* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10, 13-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

**DETAILED ACTION**

1. The following is a Final Office Action in response to communications received 11/30/2009. Claims 1-11, 13-43, 74, and 95 are pending. Claims 1, 8, 10, and 13 are amended. Claims 11, 16-43, 74, and 95 are withdrawn. Claim 12 is now cancelled and claims 44-73, 75-94, and 96-101 were previously cancelled. Elected claims 1-10 and 13-15 are examined and addressed below.

***Response to Amendment***

2. Applicant's amendments to the specification are sufficient to overcome the specification objections set forth in the previous office action.

3. Applicant's amendment to claim 15 is sufficient to overcome the claim objections set forth in the previous office action.

4. Applicant's amendments to claims 8, 10, and 13 are sufficient to overcome the 35 USC 112, second paragraph rejections set forth in the previous office action.

***Claim Objections***

5. Claim 2 is objected to because of the following informalities: the first limitation set forth in dependent claim 2 recites: "...the wire is shaped to bias the distal end of the tip assembly in a first orientation including an arcuately curved shaped having a bias radius of curvature..." and claim 1 recites the limitation of "...a wire...shaped to bias the tip assembly in a first orientation including a curved shape...". Since "arcuate" means

curved, the first limitation recited in claim 2 is not further limiting the parent claim.

Appropriate correction is required.

***Claim Rejections - 35 USC § 102***

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

**7. Claim 1 is rejected under 35 U.S.C. 102(e) as being anticipated by Coleman et al. (2002/0165441).**

**8.** Concerning **claim 1**, Colemen et al. disclose **an electrophysiology catheter** (catheter illustrated in Fig. 1; [0002]) **comprising:**

**a handle having a distal end and a proximal end, the handle including an actuator** (handle 16 has a proximal and distal end and includes an thumb control actuator 116; [0061]-[0062], Fig. 1 and 9)**;**

**a flexible shaft having a proximal end and a distal end and a longitudinal axis that extends along a length of the shaft, the proximal end of the shaft being attached to the distal end of the handle** (flexible catheter shaft 12 has a proximal end connected to handle 10 and a distal end at 38, and has a longitudinal axis; Fig. 1-2; [0030], Lines 4-5, Fig. 1)**;**

**a tip assembly having a proximal end and a distal end, the proximal end of the tip assembly being attached to the distal end of the shaft, and the tip assembly including a wire formed of a superelastic material and shaped to bias the tip assembly in a first orientation including a curved shape** (tip mapping assembly 17 includes straight proximal region 38, circular main region 39, and generally straight distal region 40 and has a proximal end that is attached to the distal end of the shaft and a distal end at 40, and includes a support member wire 24 formed of superelastic material shaped to bias the tip assembly in a first orientation include a curved shape; [0040], Fig. 4-7)**; and**

**a cable, attached to the actuator and the tip assembly, that extends through the shaft, the cable being adapted to change an orientation of the tip assembly from the first orientation in response to movement of the actuator** (the cable is taken to be either of the puller wires 64 that extend through the shaft, and are attached to the tip assembly at the tips proximal end via crosspieces 82 and to thumb control actuator 116, which when moved relative to the handle housing 102 and core 104, deflects the intermediate section, thus changing the tip assembly from the first orientation; [0061]-[0062], Fig. 2-3)**.**

### *Claim Rejections - 35 USC § 103*

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

11. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

**12. Claims 1-3, 5-6, and 14-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Avitall (5,642,736, cited in IDS) in view of Lennox (5,575,772) and in view of Accorti, Jr. et al. (5,810,887).**

**13.** Concerning **claim 1**, Avitall discloses **an electrophysiology catheter** (biplanar tissue ablation catheter system; Fig. 1) **comprising:**

**a handle having a distal end and a proximal end, the handle including an actuator** (handle 10 has a distal and proximal end and includes a longitudinal actuating handle 24 and deflection control knob 28; Column 6, Lines 11-15 and 18-24, Fig 1)**;**

**a shaft having a proximal end and a distal end and a longitudinal axis that extends along a length of the shaft, the proximal end of the shaft being attached to the distal end of the handle** (catheter shaft includes proximal central tubular section 12 that is connected to handle 10 and distal flexible maneuverable section 14, and has a longitudinal axis; Fig. 1-2)**;**

**a tip assembly having a proximal end and a distal end, the proximal end of the tip assembly being attached to the distal end of the shaft, and the tip assembly including a wire formed of a superelastic material and shaped to bias the tip assembly in a first orientation** (tip assembly 14 has a proximal end at 38 that is attached to shaft 12 and a distal end at ablation electrode 42, and includes a wire formed of superleastic material and shaped to bias the tip assembly in a first orientation; Column 3, Lines 49-58, Fig. 1-2)**; and**

**a cable, attached to the actuator and the tip assembly, that extends through the shaft, the cable being adapted to change an orientation of the tip assembly from the first orientation in response to movement of the actuator** (the cable is taken to be either of the following: wire 64 extends through the shaft to the tip assembly and causes lateral tip deflection upon rotation of lateral control knob 28, thus changing the orientation of the tip assembly from a first orientation; or wire 62 extends through the shaft to the tip assembly and causes vertical tip deflection upon sliding movement of

handle member 18, thus changing the orientation of the tip assembly from a first orientation; Column 6, Lines 11-15 and 19-24; Fig. 1) .

Avitall fails to disclose a flexible shaft. However, Lennox discloses an electrophysiology catheter that has a shaft (10) comprised of flexible proximal section (12) and distal flexible section (14) (Column 1, Lines 8-9, Column 4, Lines 10-19; Fig. 1). At the time of the invention, it would have been obvious to one of ordinary skill in the art to use a flexible shaft in order to provide the benefit of having the ability to maneuver the catheter through a vascular system as taught by Lennox (Column 4, Lines 13-15).

Avitall discloses pre-shaping the tip into specialized shapes to access and address specific internal cardiac areas (Column 3, Lines 49-58), but fails to explicitly disclose the tip assembly being biased in a curved first orientation. However, Accorti, Jr. et al. disclose pre-shaping the distal end of an electrophysiology catheter (4) into a curve (Column 1, Lines 12-13, Column 10, Lines 18-20; Fig. 2). At the time of the invention, it would have been obvious to one of ordinary skill in the art to pre-shape the tip into a curve in order to facilitate the placement of the distal portion into the heart and/or within the vessels as taught by Accorti, Jr. et al. (Column 10, Lines 18-22).

14. Concerning **claims 2 and 5**, as discussed above, Avitall as modified by Lennox and Accorti, Jr. et al. disclose the wire to be pre-shaped, or biased, into a curve, or a first orientation. The curve, and any curve, has a radius of curvature, and thus, since the curve is pre-shaped, it has a biased radius of curvature. Avitall further discloses that rotation of actuator knob (28) applies rotation torque to the control wire (64), which is transmitted tip (42), and is thus capable of changing the radius of curvature of the tip

assembly to a radius of curvature that is either smaller or larger than the bias radius of curvature (Column 6, Lines 25-38 and 48-51).

15. Concerning **claims 3 and 6**, while Avitall discloses the cable (64) located in the center of the catheter and the use of a superelastic wire within the tip, Avitall is silent as to the location of the wire. However, it would have been obvious to one having ordinary skill in the art at the time the invention was made to locate the superelastic wire and cable in the center of the catheter such that, when torqued, the radius of curvatures are equal, since it has been held that rearranging parts of an invention involves only routine skill in the art. *In re Japikse*, 86 USPQ 70.

16. Concerning **claims 14-15**, Avitall discloses the wire to be made of the nickel titanium compound Nitinol (Column 3, Lines 54-55).

**17. Claims 4 and 7-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Avitall (5,642,736, cited in IDS) in view of Lennox (5,575,772) and in view of Accorti, Jr. et al. (5,810,887), as applied to claims 1-2, in further view of Jaraczewski et al. (5,938,694, cited in IDS).**

18. Concerning **claims 4 and 7**, Avitall as modified by Lennox and Accorti, Jr. et al. fail to disclose the biased first orientation to be an arcuately curved shape spanning at least three hundred and sixty degrees. However, Jaraczewski et al. disclose an electrophysiology catheter with a distal tip assembly (24) pre-shaped by a superelastic core (14) that is biased in a coiled conical shape with one or more curved regions curving more than 360 degrees (Column 5, Lines 4-5, 24-25, and 28-29; Fig. 1-2, 4). At

the time of the invention, it would have been obvious to one of ordinary skill in form the pre-shaped curve to a curve of at least 360 degrees in order to provide the benefit of producing an array of electrodes designed to engage only a portion of the chamber wall of the heart so that a relatively large surface area of the heart can be mapped precisely and in a relatively short time span and to improve access to target sites for ablation as taught by Jaraczewski (Column 1, Lines 60-64, Column 3, Lines 42-46).

19. Concerning **claims 8 and 10**, while Avitall discloses pre-shaping the tip into specialized shapes to access and address specific internal cardiac areas (Column 3, Lines 49-58), Avitall as modified by Lennox and Accorti, Jr. et al. fail to explicitly disclose biasing the tip in a first orientation that includes a bend having a bias angle of ninety degrees relative to the longitudinal axis of the shaft. However, Jaraczewski et al. disclose an electrophysiology catheter with a distal tip assembly (24) pre-shaped by a superelastic core (14) that is biased with an angle of ninety degrees relative to the longitudinal axis of the shaft (Fig. 1, 2A). At the time of the invention, it would have been obvious to one of ordinary skill in the art bias the tip with a ninety degree angle relative to the shaft's longitudinal axis in order to provide the benefit of producing an array of electrodes designed to engage only a portion of the chamber wall of the heart so that a relatively large surface area of the heart can be mapped precisely and in a relatively short time span and to improve access to target sites for ablation (i.e., pulmonary vein ostium) as taught by Jaraczewski (Column 1, Lines 60-64, Column 3, Lines 42-46). Avitall further discloses cable (62) that causes vertical tip deflection through sliding movement of handle member (18) (Column 6, Lines 15-24; Fig. 1). The

cable (62) is capable of changing the angle of the bend to an angle smaller or larger than or equal to the bias angle in response to movement of actuator (18).

20. Concerning **claim 9**, while Avitall discloses the cable (64) located in the center of the catheter and the use of a superelastic wire within the tip, Avitall is silent as to the location of the wire. However, it would have been obvious to one having ordinary skill in the art at the time the invention was made to locate the superelastic wire on the inner portion of the catheter with the cable being disposed in an outer portion (where outer is defined as "on or around the outside of something"; Encarta Online Dictionary) with respect to the angle of bend of the proximal end, since it has been held that rearranging parts of an invention involves only routine skill in the art. *In re Japikse*, 86 USPQ 70.

**21. Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Avitall (5,642,736, cited in IDS) in view of Lennox (5,575,772) and in view of Accorti, Jr. et al. (5,810,887), as applied to claim 1, and in further view of Ponzi (6,254,568).**

22. Concerning **claim 13**, Avitall as modified by Lennox and Accorti, Jr. et al. fail to disclose the wire shaped to bias the proximal end in a linear orientation. However, Ponzi discloses a catheter deflectable via a puller cable (32) that is capable of deflecting proximal section of distal tip (14) (Column 4, Lines 21-26; Fig. 1). The proximal end is biased with straightening element (50) in a linear orientation in order to avoid permanent deformation of the tip in the form of a residual tip curve (Column 4, Lines 49-53; Claims 1 and 7). At the time of the invention it would have been obvious to one of ordinary skill

in the art to bias the proximal end of the distal tip in a linear orientation in order to provide the benefit of eliminating the "residual tip curve" problem as taught by Ponzi (Column 4, Lines 49-53). Avitall further discloses cable (62) that causes vertical tip deflection through sliding movement of handle member (18) (Column 6, Lines 15-24; Fig. 1). The cable (62) is capable of changing the angle of the bend to an angle smaller or larger than or equal to the bias angle in response to movement of actuator (18).

***Response to Arguments***

23. Applicant's arguments with respect to claims 1-10 and 13-15 have been considered but are moot in view of the new ground(s) of rejection.

***Conclusion***

24. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JAYMI DELLA whose telephone number is (571)270-1429. The examiner can normally be reached on M-Th 7:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on (571)272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Linda C Dvorak/
Supervisory Patent Examiner, Art Unit 3739

/J. D./
Examiner, Art Unit 3739
February 2, 2010